

REMARKS

Amendment to the Specification

The Examiner objected to some language in the abstract of the disclosure of the specification. The particular language of the abstract has been amended to include the Examiner's suggestions.

Claim Objections

At the time of the Office Action, claims 1, 2, 6, and 11-15 were objected to for improper form.

The Examiner objected to Claim 1 for the limitation "the elongated circuit" in line 3 of the claim, which had insufficient antecedent basis. The Applicant corrected the language to read "the elongated conduit" as suggested by the Examiner.

The Examiner objected to Claim 2 for the limitation "fiberoptic" in line 2 of the claim, which had insufficient antecedent basis. The Applicant corrected the language to read "optical fiber" as suggested by the Examiner.

The Examiner objected to Claim 6 for the limitation "the physiological property" in line 1 of the claim, which had insufficient antecedent basis. The Examiner stated that for purposes of examination, Claim 6 is considered to depend from Claim 5. The Applicant corrected the language so that Claim 6 is now dependent upon Claim 5, as suggested by the Examiner.

The Examiner objected to Claim 11 for the limitation "second and fourth optical fibers" in line 2 of the claim, which had insufficient antecedent basis. The Examiner stated that for purposes of examination, Claim 11 is considered to depend from Claim 10. The Applicant corrected the language so that Claim 11 is now dependent upon Claim 10, as suggested by the Examiner.

The Examiner objected to Claim 12 for the limitation "the component" in line 1 of the claim, which had insufficient antecedent basis. The Applicant corrected the language to read "the first optical fiber" as suggested by the Examiner.

The Examiner objected to Claims 13-15 for the limitation "the component" in each claim, which had insufficient antecedent basis. The Examiner stated that for purposes

of examination, Claims 13-15 are considered to depend from Claim 12. The Applicant corrected the language so that Claims 13-14 are now dependent upon Claim 12, as suggested by the Examiner. Claim 15 has been cancelled, without prejudice.

The Examiner objected to Claims 6 and 11 because the preamble recites "The system of Claim 1," which had insufficient antecedent basis and was inconsistent with the preambles of the other claims. The Applicant corrected the language to read "The surgical drain of claim 1" as suggested by the Examiner.

Claim Rejections, 35 USC 102

At the time of the Office Action, claims 1-15 were pending. The Examiner rejected claims 1-7, 9, 10 and 12-15. Claims 1-6, 9-10 and 12-15 were rejected under 35 U.S.C. 102(b) as being anticipated by Johnson (US 3,866,599). Claims 4 and 15 have been cancelled without prejudice. The Applicant respectfully traverses the rejections.

Independent claim 1 of the present application has been amended to claim a surgical drain comprising an elongated conduit to be implanted in and to drain fluid from a patient's body; a first optical fiber having a first optical fiber distal end, wherein the distal end branches from the conduit and is configured for insertion in tissue proximate to the conduit and configured to deliver energy to the tissue; and a second optical fiber having a second optical fiber distal end configured to receive energy from the tissue. Johnson does not disclose a surgical drain having an optical fiber, wherein the distal end of the optical fiber branches from the conduit and is configured for insertion into tissue.

Rather, Johnson discloses that the optical fibers embedded within an intravascular catheter *irradiate blood and collect the reflected* light from the blood to determine oxygenation saturation of the blood.

In addition, the Examiner stated that Johnson discloses a surgical drain configured to be implanted in and to drain from a body cavity. However, Johnson does not disclose a device to *drain* fluid from the body, as disclosed in independent claim 1 of the present application. Neither column 1 lines 7-10 (as pointed out by the Examiner), nor the rest of the Johnson patent disclose a *draining* function. Rather, Johnson

discloses that a user may manually couple a syringe with the coupling element 6 to take a blood sample or use a saline solution to flush the catheter. These user-intensive, manual flushing and blood sampling procedures do not anticipate the draining disclosed in the present application. The effect of draining is significant removal of unwanted fluids, which is not the case for useful blood circulating within the vessels. Furthermore, it is not inherent that the Johnson device would drain body fluids. Rather, the intravascular catheter would overload the coupling element 6 and a user would have to constantly remove the blood samples from the coupling element 6 in order for the intravascular catheter of Johnson to function as a *drain*.

The Examiner also rejected dependent claim 4, stating that the elongated conduit 2 of Johnson further comprises a housing 20 extending from the conduit 2. The applicant traverses this rejection. The housing 20 that the Examiner points out in Johnson does not extend from the conduit as in the present application. Rather, the housing 20 that the Examiner points to is actually described as a “wall” (column 3, line 8 of Johnson), which forms the conduit. However, in the present application, the housing extending from the conduit facilitates insertion of the transmitting optical fiber *into* the tissue, while the conduit portion rests *against* the tissue from which fluids are drained. Johnson does not disclose such a configuration; Johnson does not disclose a housing extending from the conduit that supports an optical fiber for insertion into tissue.

Claim 5 has been amended to include the limitation that the energy received by the second optical fiber distal end has at least one characteristic indicative of at least one physiological property of the tissue. This does not present new matter, is cited in paragraph 52 of the specification and is allowable since claim 5 depends from independent claim 1.

Claim 8 has been amended to remove the limitation that the second optical fiber distal tip is embedded “behind material that is optically transparent.” This does not present new matter, and is allowable since claim 8 depends from independent claim 1.

Thus, Johnson does not anticipate the surgical drain of independent claim 1, or the dependent claims 2-14, since Johnson does not disclose a surgical drain comprising an elongated conduit configured to be implanted in an to drain fluid from a patient's

body; a first optical fiber having a distal end that extends from the conduit and that is configured for insertion in tissue and configured to deliver energy to the tissue; and a second optical fiber having a second optical fiber distal end configured to receive energy from the tissue.

Claim Rejections, 35 USC 103

The Examiner also rejected claim 7 under 35 U.S.C. 103(a) as being unpatentable over Johnson (US 3,866,599) in view of Russo et al. (US 4,317,452). The Applicant respectfully traverses the rejection. To establish a *prima facie* case of obviousness, three basic criteria must be met (MPEP §2143). First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings (MPEP §2143.01). Second, there must be a reasonable expectation of success (MPEP §2143.02). Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations (MPEP §2143.03).

First, there is no suggestion or motivation to combine or modify the prior art cited by the Examiner. One would not be motivated, as suggested by the Examiner, to “provide the surgical drain of Johnson with a plurality of holes, as taught by Russo et al.” Surgical drains and intravascular catheters are not within the same field. Johnson’s intravascular catheter would be harmful to patients if it were used as a drain blood from a blood vessel. Surgical drains are intended for the removal of unwanted body fluids, which is not the case for the useful blood circulating within the vessels. Furthermore, the catheter of Johnson would not work if holes were placed along its length. As stated earlier, Johnson’s intravascular catheter would overload the coupling element 6 and the user would have to constantly remove the blood samples from the coupling element 6 in order for the intravascular catheter of Johnson to function as a *drain*.

In addition, Russo et al. and Johnson in combination do not teach or suggest all of the elements of claim 7. The prior art cited by the Examiner does not teach or suggest a surgical drain having an optical fiber, wherein the distal end of the optical fiber extends from the conduit and is configured for insertion into tissue; wherein the conduit includes a drain portion configured to rest against a substantial length of tissue

within the body and a plurality of drain holes spaced along substantially the entire length of the drain portion.

Allowable Subject Matter

The Examiner objected to claims 8 and 11 as being dependent upon a rejected base claim, and stated that they would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. As discussed above, independent claim 1 and intervening claim 10 is allowable; thus, dependent claims 8 and 11 are allowable.

New Claims 16-19

New independent claim 16 discloses a surgical drain comprising an elongated conduit configured to be implanted in and to drain fluid from a patient's body; an energy source configured for insertion in tissue proximate to the conduit and configured to deliver energy to the tissue; and an energy receiver that receives energy from the energy source after the energy passes through the tissue in transmission mode. Claim 16 does not present any new matter, and is supported by paragraphs 65 and 66 and figures 4A and 4B of the present application. The surgical drain's substantially opposing positioning of the energy-transmitting and energy-receiving optical fibers allows the light to travel from the energy-transmitting optical fiber through the tissue and into the energy-receiving optical fiber in transmission mode. Claim 16 is not taught or suggested by the prior art cited by the Examiner, and thus is allowable. Claims 17-19 depend upon claim 16, and thus are allowable.

CONCLUSION

For all the above reasons, the Applicant submits that the application is in condition for allowance, which action it respectfully solicits.

A petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 501946, please credit any excess fees to such deposit account and please reference attorney docket number 64693-097.

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